

NIH Workshop: Quantitative Systems Pharmacology and Drug Discovery: Filling the Gaps in Current Models of the R&D Process for Neurotherapeutics

NIH Institute Directors:

Walter Koroshetz, M.D.

NINDS, Director

Dr. Walter J. Koroshetz, M.D., was selected Director of National Institute of Neurological Disorders and Stroke (NINDS) on June 11, 2015. Dr. Koroshetz joined NINDS in 2007 as Deputy Director, and he served as Acting Director from October 2014 through June 2015. Previously, he served as Deputy Director of NINDS under Dr. Story Landis. Together, they directed program planning and budgeting, and oversaw the scientific and administrative functions of the Institute. He has held leadership roles in a number of NIH and NINDS programs including the NIH's BRAIN Initiative, the Traumatic Brain Injury Center collaborative effort between the NIH intramural program and the Uniformed Health Services University, and the multi-year work to develop and establish the NIH Office of Emergency Care Research to coordinate NIH emergency care research and research training.

Richard Hodes, M.D.

NIA, Director

Dr. Richard J. Hodes is the Director of the National Institute on Aging (NIA) at the National Institutes of Health (NIH). The NIA is the principal Federal funding agency for studies of the basic, clinical, epidemiological, and social aspects of aging. Dr. Hodes was named Director of the NIA in 1993.

Dr. Hodes maintains an active involvement in research on the NIH campus in Bethesda, Maryland, through his direction of the Immune Regulation Section of the National Cancer Institute, a laboratory devoted to studying regulation of the immune system, focused on cellular and molecular events that activate the immune response. This involvement in campus research also serves to strengthen ties with other NIH scientists involved in studies of age-related diseases.

Dr. Hodes received his B.A. from Yale University in 1965 and his M.D. from Harvard Medical School in 1971. He is a Diplomate of the American Board of Internal Medicine. In 1995, Dr. Hodes was elected as a member of The Dana Alliance for Brain Initiatives; in 1997, he was elected as a Fellow of the American Association for the Advancement of Science; and, in 1999, he was elected to membership in the Institute of Medicine of the National Academy of Sciences. As author of more than 250 research papers, he is an influential scientist in and contributor to the field of immunology.

NINDS Division Director:

Amir Tamiz, Ph.D.

Associate Director, Division of Translational Research

Dr. Tamiz is the Director of the Division of Translational Research at the National Institute of Neurological Disorders and Stroke (NINDS). Prior to that he was a program director overseeing the NIH Blueprint Neurotherapeutics network (BPN) and Innovation Grants to Nurture Initial Translational Efforts (IGNITE). Blueprint Neurotherapeutics network is a collaborative effort among 15 of the agency's institutes and centers, leveraging their resources to offer neuroscience researchers grant funding for drug discovery and development activities to confront major, cross-cutting challenges in neuroscience. The program was established as a pipeline between academic and industry drug development research and offers neuroscience researchers a "virtual pharma" to develop promising hit compounds from chemical optimization through Phase I clinical testing. Principal Investigators receive grant funding and in kind discovery and development resources such as medicinal chemistry, API synthesis and manufacture, formulation and drug product manufacture, IND enabling studies, and clinical trial capabilities. Launched in December 2014, IGNITE program is intended to create a more contiguous source of support from discovery to preclinical development. The first two programs include: 1) Assay Development and Therapeutic Agent Identification and Characterization to Support Therapeutic Discovery (PAR-15-070) and 2) Pharmacodynamics and In vivo Efficacy Studies for Small Molecules and Biologics/Biotechnology Products (PAR-15-071). Prior to joining NIH in 2012, Dr. Tamiz had held scientific and management positions in research and development of therapeutic programs at Corvas

International (acquired by Dendreon), CovX (now part of Pfizer), and Alba Therapeutics. Dr. Tamiz received his Ph.D. at University of Oregon and conducted postdoctoral research at the Department of Neuroscience at Georgetown University Medical Center.

Workshop Chairs:

Mary Ann Pellemounter, Ph.D.

Dr. Pellemounter is a Program Director in the Division of Translational Research at NINDS. She leads the IGNITE Drug Discovery extramural grant program and is a scientific project manager for the Blueprint Neurotherapeutics program. She has over 25 years of experience in scientific research and over 20 years of experience in drug discovery and development. Mary Ann's scientific training is in the field of behavioral neuroscience with a focus on age-related cognitive dysfunction, neurodegeneration and neuropharmacology. She received her PhD at the University of Colorado and conducted her post-doctoral research at the University of North Carolina (Chapel Hill) in the laboratory of Dr. Michela Gallagher. Following her post-doctoral work, Dr. Pellemounter focused her research on drug discovery and development in the therapeutic areas of neurodegeneration and neuropsychiatry until the mid-1990s when she shifted her research emphasis to obesity and metabolic disease therapeutics. Since that time, Dr. Pellemounter moved to scientific leadership roles, directing in vivo pharmacology at Neurocrine Biosciences and leading the biology drug discovery effort for obesity therapeutics at Bristol Myers Squibb. During Dr. Pellemounter's tenure as Director of Obesity Therapeutics, her department progressed multiple compounds into clinical development and helped to restructure the focus of their drug discovery efforts to better complement the existing efforts in diabetes and metabolic disease. Dr. Pellemounter has over 60 published original research articles, reviews and book chapters, is the author of multiple published patents relating to the discovery and use of leptin and has received numerous research grants and awards in the fields of cognition, aging and neuropsychiatry.

Suzana Petanceska, Ph.D.

Dr. Petanceska joined the National Institute on Aging in 2005, as a program director in the Division of Neuroscience. During her tenure at the NIA she has been overseeing and developing a number of research portfolios and programs in basic and translational research for Alzheimer's disease. She has been instrumental for the development of NIA's AD Translational Research program, the Epigenomics of AD portfolio and the Accelerated Medicines Partnership for AD (AMP-AD) – Target Discovery and Preclinical Validation Project. Since 2012 she has been leading a number of NIA's strategic planning activities related to achieving the research goal of the National Plan to Address Alzheimer's: to prevent and treat AD by 2025.

Dr. Petanceska is a graduate of the University of Belgrade in the former Yugoslavia, where she received a bachelor's degree in molecular biology and physiology. She holds a Ph.D. in Pharmacology from New York University. Following her postdoctoral training at Rockefeller University and Cornell University in New York, she established her independent research career at the Nathan Kline Institute in Orangeburg, N.Y., and joined the faculty of New York University Medical Center. Her research focused on the role of disrupted sterol metabolism in Alzheimer's disease pathogenesis and on the mechanisms by which estrogens and cholesterol-lowering drugs might exert neuroprotection.

Piet van der Graaf, Ph.D.

Dr. Piet van der Graaf, PharmD PhD is professor of Systems Pharmacology at University of Leiden (The Netherlands) and vice president and head of Quantitative Systems Pharmacology (QSP) at Certara. From 1999-2013 he held various leadership positions at Pfizer in Sandwich (United Kingdom) in Discovery Biology (Head of Sexual Health Therapeutic Area), Pharmacokinetics and Drug Metabolism (Head of Translational Quantitative Pharmacology) and Clinical Pharmacology/Pharmacometrics (responsible for the Pain research portfolio). He was involved in a large number of drug discovery and development programs in multiple therapeutic areas and responsible for the nomination of more than 10 clinical development candidates. He holds several patents in the field of target discovery.

He received his doctorate training in quantitative pharmacology with Nobel laureate Sir James Black at King's College London and worked as a postdoctoral fellow of the Royal Netherlands Academy of Sciences at the University of Leiden on the development of mechanism-based PKPD approaches. He is Editor-in-Chief of CPT: Pharmacometrics & Systems Pharmacology (www.cpt-psp.com), a Fellow of the British Pharmacological Society and a F1000 member of the newly established Systems & Network Biology Faculty. He has co-authored more than 100 papers in the area of quantitative and translational pharmacology. He was the only non-US-based author of the seminal 2011 NIH White Paper Quantitative and Systems Pharmacology in the Post-genomic Era. He has been involved in various pre-competitive public-private partnerships in the area of quantitative pharmacology/toxicology such as the Top Institute Pharma "PKPD Platform" consortium and recent European IMI programs DDMoRe, K4DD and TransQST. He is member of the scientific advisory boards of several pharmaceutical and biotech companies and not-for-profit organisations. He is member of the ISoP steering committee Special Interest Group on Systems Pharmacology, member of the AAPS Systems Pharmacology Focus Group and member of the IQ Consortium Clinical Pharmacology Leadership Group QSP working group.

Workshop Speakers:

Jane Bai, Ph.D.

Dr. Bai is a regulatory review scientist with expertise in systems pharmacology in the Office of Clinical Pharmacology, Center for Drug Evaluation and Research, Food and Drug Administration. Dr. Bai joined FDA in August, 2005, as a pharmacologist reviewing regulatory submissions of drug applications. In 2010, she joined Office of Clinical Pharmacology's predictive safety efforts, and has since been working on systems pharmacology-based predictive assessment of drug safety. Dr. Bai received a master degree in applied mathematics in 1989 and Ph.D. in pharmaceuticals in 1990 from the University of Michigan, Ann Arbor, Michigan. Prior to joining the FDA, she was on the faculty of the Pharmaceuticals Department until March, 1996, at the University of Minnesota, and was named PhRMA Starter (1992) and AAPS Young Investigator (1994). From 1996 to 2004, she was an entrepreneur exploring biotech ventures, and received NIH and state funding for these endeavors. She licensed to several pharmaceutical companies an in-silico software,

OraSpotter®, which was developed using a database of 1,200 drugs/human oral pharmacokinetics for predicting the fraction dose absorbed in humans. She initiated and co-founded the FDA's Systems Pharmacology Scientific Interest Group in 2016. In addition to contributing to FDA's mission, she has published 60 peer-reviewed papers and book chapters.

James Baurley, Ph.D.

Dr. Baurley educational background is computer science (Clemson University) and statistical genetics (University of Southern California). He started a consulting company called BioRealm while earning his PhD. Back then, we helped researchers set up their studies and analyze their data. That is still our primary focus, but the data is more complex and there is a lot more. My own research interest is on statistical computing in genomics. Recently, we developed a genotyping platform for the NIH designed to characterize the genetics of addiction. We are now applying novel algorithms to that data to learn models intended to help smokers quit and reduce risk in opioid users. My recent publications can be found at <http://biorealm.ai/research/>

Gerome Breen, Ph.D.

Dr. Gerome Breen is a psychiatric geneticist who works on the genetics of affective (mood) disorders, psychosis and eating disorders. He has recently begun new research into eating disorders, leading the academic work of the Charlotte's Helix project [www.charlotteshelix.net]. Within the Psychiatric Genomics Consortium (PGC), he has done substantial work on major depressive disorder and bipolar disorder. We are now finally finding genetic variants related to these disorders, thanks to massive increases in sample size. For example, we're now working with more than 130,000 depression cases and 300,000 controls. Dr. Breen also chair (with his close collaborator Cindy Bulik) the PGC Anorexia and Eating Disorders group, where they are beginning to find genetic hits for Anorexia nervosa, the most lethal psychiatric disorder. Another of his main research interests is uncovering biological pathways using large scale genetic data, work which he undertakes as chair of the PGC Network and Pathway Analysis group. This work has recently been extended to focus on how they can identify new drugs and known drug targets from GWAS data.

Owen Carmichael, Ph.D.

Dr. Owen Carmichael is the Director of the Biomedical Imaging Center at the Pennington Biomedical Research Center, which is part of Louisiana State University in Baton Rouge, LA. His research focuses on developing new biomedical imaging techniques and applying them to aging and cardiometabolic health.

Rima, Kaddurah-Daouk

Dr. Kaddurah-Daouk has been a seminal force in the development and evolution of the metabolomics field. She co-founded the Metabolomics Society, served as its founding president and for over five years organized national and international meetings and workshops to establish foundations and community for metabolomics research. Also cofounded a leading biotechnology company devoted to metabolomics applications. With funding from NIGMS, non profit and for profit organizations and in partnership with the Pharmacogenomics Research Network (PGRN) she established and led the Pharmacometabolomics Research Network (PMRN). The two networks working collaboratively established foundations and tools to enable “Quantitative Systems Pharmacology” and “Precision Medicine” approach where omics data is used to define at a deeper level mechanism of action of drugs, mechanism of variation of response to treatment and where drugs are used as probes to understand disease mechanisms and disease heterogeneity. Metabolomics data led to totally new insights about drugs used for treatment of neuropsychiatric and cardiovascular diseases. A role for the gut microbiome was identified in response to statins; metabolic signatures revealed differences in how blacks and whites respond to beta blockers and how men and women respond differently to aspirin.

The Mood Disorder Precision Medicine Consortium that she leads with funding from NIMH is applying “Pharmacometabolomics informs Pharmacogenomics” approaches to gain deeper understanding of sub clinical phenotypes in major depression. Molecular signatures have been identified for characterizing resistant type of depression and for providing insights about delayed and varied response to SSRIs steps towards discovering more effective therapies for treatment of depression.

Dr. Kaddurah-Daouk leads the Alzheimer Disease Metabolomics Consortium (ADMC). This consortium is funded by NIA under the flagship of AMPAD and M2OVEAD national programs. In partnership with the Alzheimer Disease Neuroimaging Initiative (ADNI) ADMC is implementing a systems approach to the study of AD where metabolomics data is used along with genomics proteomics and imaging data to define metabolic failures across the trajectory of disease. Sex differences in the metabolomes of men and women are being highlighted to try to explain different trajectory of disease. All biochemical knowledge gained from consortium is used to connect peripheral and central changes steps to define novel targets for drug design and blood biomarkers that inform about disease.

Joel Dudley, Ph.D.

Dr. Dudley is a recognized leader in applying biomedical Big Data to healthcare and drug discovery. He currently holds positions as Associate Professor of Genetics and Genomic Sciences and Director of Biomedical Informatics at the Icahn School of Medicine at Mount Sinai. He also directs the newly formed Institute for Next Generation Healthcare at Mount Sinai. Prior to Mount Sinai, he held positions as Co-founder and Director of Informatics at NuMedii, Inc., one of the first companies to apply Big Data to drug discovery, and Consulting Professor of Systems Medicine in the Department of Pediatrics at Stanford University School of Medicine. His work is focused on developing and applying advanced computational methods to integrate the digital universe of information to build better predictive models of disease, drug response. He and his team are also developing pioneering methods to bring about a next generation of medicine that leverages advances in diagnostics, wearables, digital health to enable new approaches to precision medicine and scientific wellness. He has authored and co-authored more than 80 publications and his research has been featured in the Wall Street Journal, Scientific American, Forbes, and other popular media outlets. His recent work using a Big Data approach to identify sub-types of Type 2 diabetes was recently highlighted by NIH director Francis Collins on the the NIH Director's Blog as a significant advance in precision medicine. He was named in 2014 as one of the 100 most creative people in business by Fast Company magazine. He is co-author of the book Exploring Personal Genomics from Oxford University Press, which is used as a text in personalized and precision medicine courses at universities worldwide. He holds an MS and PhD

in Biomedical Informatics from Stanford University School of Medicine. Dr. Dudley serves on the Scientific Advisory boards of numerous startups and companies in biotech and healthtech.

Steve Finkbeiner, M.D., Ph.D.

As one of the first investigators to join the Gladstone Institute of Neurological Disease in 1999, Dr. Finkbeiner is best known for his pioneering work on neurodegenerative diseases. He invented robotic microscopy, a new form of imaging that has helped unravel cause-and-effect relationships in amyotrophic lateral sclerosis (ALS, or Lou Gehrig's disease), Huntington's, Alzheimer's and other neurodegenerative diseases. Dr. Finkbeiner used his robotic microscope to resolve a long-standing puzzle in Huntington's disease. A study based on results from the microscope became the most-cited paper in the field of neuroscience in the last decade.

Hugo Geerts, Ph.D.

Dr. Hugo Geerts spent 17 years in the (CNS) Drug Discovery with Dr. Paul Janssen, probably the greatest drug hunters in history at the Janssen Research Foundation in Beerse, Belgium doing research in Alzheimer's disease with targets in tau and amyloid pathology. He was involved in supporting the successful preclinical, clinical and postmarketing development of galantamine for Alzheimer's Disease. In 2002 he co-founded In Silico Biosciences, a company providing mathematical modeling of pathological interactions in the brain for supporting the whole process of Drug Discovery – from Target validation to clinical trial design - in Psychiatry and Neurology. He is on the faculty of the University of Pennsylvania, Perelman School of Medicine and Drexel Dept. of Pharmacology and has over 100 peer-reviewed publications and patents.

Nancy Klimas, M.D.

Dr. Nancy Klimas directs the Environmental Medicine Program at the Miami VAMC and the NSU Institute for Neuro-Immune Medicine, a multi-disciplinary research and clinical program that is taking a systems biology approach to understanding complex medical illnesses. NSU INIM partners with the Miami VAMC to study Gulf War Illness and ME/CFS; the institute brings 62 investigators, clinicians, and support staff working together to deliver targeted therapy for complex medical conditions.

Dr. Klimas is a diplomat of the American Board of Internal Medicine, and Diagnostic Laboratory Immunology. She is a practicing clinician, having cared for thousands of ME/CFS and GWI patients, inspiring this research focus. She is a founding member and past president of the International Association for CFS and Myalgic Encephalomyelitis (IACFS/ME), a professional organization of clinicians and investigators, and received its highest honor in 2013, the Perpich Award for contributions to the field. She has served on the Health and Human Services (HHS) CFS Advisory Committee for 11 years. She was a member of the Institute of Medicine's ME/CFS Case Definition committee and the NIH P2P committee, and is a member of the NASA Immunology Integration Committee.

She has designed and will be implementing a proof of concept phase 1 study in GWI using the team's computationally modeled trials system and animal modeling pre-clinical testing to develop strategies to "reboot" homeostatic networks in GWI.

Peter Lansbury, Ph.D.

Dr. Peter Lansbury is Chief Scientific Officer of Lysosomal Therapeutics, Inc. He graduated from Princeton University and received his PhD from Harvard University. After a postdoctoral fellowship at the Rockefeller University, he joined the faculty of the Department of Chemistry at MIT. He moved to the Harvard Medical School in 1996 and was promoted to Professor of Neurology in 2004. He was the founding director of the Morris K. Udall NIH Parkinson's Disease Research Center of Excellence. He founded Link Medicine and served as its Chief Scientific Officer from 2005 until its sale to AstraZeneca in 2012. He is currently on leave from his position as professor of Neurology and Harvard Medical School. Peter was a National Science Foundation Presidential Young Investigator and a Zenith Fellow of the Alzheimer's Disease Association.

Allan Levey, M.D., Ph.D.

Dr. Allan Levey MD, PhD is Professor and Chair, Department of Neurology and Director of the Emory Alzheimer's Disease Research Center. He is a neuroscientist and neurologist with expertise in Alzheimer's and other neurodegenerative diseases. He leads the Emory AMP-AD project focused on proteomics discovery of novel targets for Alzheimer's disease.

Lara Mangravite, Ph.D.

Lara Mangravite, PhD is President of Sage Bionetworks. This organization focuses on the development and implementation of practices for large-scale collaborative biomedical research. This work includes new approaches to scientific process that use open systems to enable community-based research regarding complex biomedical problems. Dr. Mangravite works closely with multiple institutes at NIH to apply these approaches to advance understanding of disease biology and treatment outcomes at a systems level including in the field of Alzheimer's Disease. Dr. Mangravite obtained a BS in Physics from the Pennsylvania State University and a PhD in Pharmaceutical Chemistry from the University of California, San Francisco. She completed a postdoctoral fellowship in cardiovascular pharmacogenomics at the Children's Hospital Oakland Research Institute.

Kalpana Merchant, Ph.D.

Dr. Kalpana Merchant has deep expertise in the neurobiology of chronic neurodegenerative and psychiatric disorders. She has nearly 25 years of experience in drug discovery and development with a special emphasis on translational strategies that improve the success rate of drug development. Since March 2014, Kalpana has been providing advisory and consultancy services to non-profit institutions and startup pharmaceutical/biotechnology companies. She continues to remain engaged in training and mentoring of graduate students, postdoctoral scientists and junior faculty through her academic positions. From 1993 to 2014, Kalpana held scientific and strategic leadership/management roles in the US pharmaceutical industry. She retired from Eli Lilly from the position of Chief Scientific Officer for Tailored Therapeutics. Kalpana received her PhD in neuropharmacology from the University of Utah in 1989. Following a postdoctoral fellowship at University of Washington, she joined the same institute as Assistant Professor of Psychiatry. Kalpana is engaged in the wider scientific community via her service on the National Center for Advancing Translational Sciences (NCATS) Advisory Council and the Cures Acceleration Network Review Board for the National Institutes of Health (NIH), as an advisor to the Michael J Fox Foundation for Parkinson's Research, membership of The Wellcome Trust Review Board as well as several professional societies.

Michael Oshinsky, Ph.D.

Dr. Michael L. Oshinsky joined the NINDS in 2014 as a Program Director in Systems and Cognitive Neuroscience. Dr. Oshinsky received a B.A. in Biology with a concentration in Neuroscience from Brandeis University, where he learned electrophysiology in the laboratory of Eve E. Marder, Ph.D. He earned a Ph.D. in Neurobiology & Behavior from Cornell University in the laboratory of Ronald R. Hoy studying neural circuits. As an NIH sponsored postdoctoral fellow at the University of Pennsylvania, he trained with Gary Aston-Jones, Ph.D. in neuropharmacology and neuromodulation. He was on the faculty in the Department of Neurology at Thomas Jefferson University since 2001, before joining the NINDS. During those years he was the Director of Preclinical Research at the Jefferson Headache Center and directed an NIH funded research program aimed at developing and characterizing animal models of headache. In 2011, Dr. Oshinsky was awarded the Harold G. Wolff Award for headache research. He also taught in the Graduate Neuroscience Program and the Sydney Kimmel Medicine College at Thomas Jefferson University. As a Program Director at NINDS, Dr. Oshinsky is responsible for research and administrative issues related to migraine, other headache disorders, neuropathic pain, peripheral and central mechanisms that mediate pain, central processing of pain perception, disease-related pain disorders, and pain management.

Karen Sachs, Ph.D.

Dr. Karen Sachs' research focuses on the interface of molecular biology and machine learning, developing methods to extract maximal insight into underlying biological systems, from high dimensional datasets which defy classic interpretation by human intuition. Her expertise is causal models, probabilistic graphical models, and data integration methods. She received her PhD from MIT Bioengineering, under the tutelage of Doug Lauffenburger, and was subsequently a Leukemia and Lymphoma Society Fellow working with Garry Nolan at the Stanford University School of Medicine. She has served as a causal modeling advisor and consultant to Lifecode Inc. and Fluidigm Corporation, developing methods to interpret variants and leverage single cell data. She is Lead Data Scientist on the ALS Consortium project Answer ALS, integrating heterogeneous molecular and clinical data from consortium labs across the country, with Ernest Fraenkel at MIT.

Former applications focused primarily on cancer and immunology; Answer ALS is her first foray into neurotherapeutics.

Clemens Scherzer, M.D.

Dr. Clemens R. Scherzer, MD directs The Neurogenomics Laboratory at Harvard Medical School and Brigham and Women's Hospital, is the Co-Founder and Co-Director of the Harvard NeuroDiscovery Center Biomarkers Program, and Associate Professor of Neurology at Harvard Medical School.

The goal of the Scherzer Laboratory is to catalog and decipher all functional elements of the human genome in the human brain, and to determine how the normal flow of genetic information is corrupted in Parkinson's, Huntington's, and other neurodegenerative diseases. As physician-scientist Scherzer envisions and is building a future personalized Parkinson's health care, where DNA, RNA, and biome barcodes are used for much earlier diagnosis, personalized prognosis, tailored treatments, and response tracking.

Dr. Scherzer is the recipient of the Dr. Paul Beeson Award, the George C. Cotzias Memorial Award, and an Edmond J. Safra Global Genetics Consortium Award of the Michael J. Fox Foundation. He serves on the Editorial Boards of Neurogenetics and Biomarkers in Medicine, and on the Steering Committees of the MJFF's Parkinson Progression Marker Initiative (PPMI) as well as the NINDS' Parkinson Biomarker Program (PDBP).

James Schwaber, Ph.D.

Dr. Schwaber is a Professor of Pathology, Cell Biology and Anatomy at Thomas Jefferson University, where he is the Director of the Daniel Baugh Institute for Functional Genomics and Computational Biology. He received his BA from the University of Illinois, his PhD from the University of Miami in Neuroscience working under Dr. Neil Schneiderman, and postdoctoral training at the University of Virginia under Drs. David Cohen and John Jane. He spent 20 years in the E.I. DuPont Company where he, sequentially, (1) co-developed in the Neurobiology Group the business plan that was the platform to launch the Cephalon Pharmaceutical Company; (2) participated in the Cardiovascular Sciences group that developed the anti-hypertensive drug

losartan; (3) was awarded patents for imaging methods that were licensed to form businesses that perform neuroanatomical mapping and imaging; (4) hosted a conference in 1986 at DuPont to coordinate research among investigators interested in digital brain atlas technology that has come into use in MRI; (5) led an interdisciplinary “Core Genomics” computational biology team with projects in ag-biotech and microbial metabolism, as well as pharma; and (6) hosted a ONR-NSF-DuPont sponsored funding initiative planning workshop “Gene Networks and Cellular Controls” in 1996. In 2000, Dr. Schwaber joined the faculty of TJU and (1) initiated the computational and genomics focus of the Daniel Baugh Institute; (2) participated in the DARPA Bio-COMP initiative; and (3) received NIH BISTI initiative funding to initiate and develop a cooperative research and training program with the University of Delaware to exploit their complementary strengths in medicine and engineering.

Peter Searson, Ph.D.

Dr. Peter Searson is the Reynolds Professor of Engineering at Johns Hopkins University. He was founding Director of the Johns Hopkins Institute for Nanobiotechnology and holds joint appointments in the Department of Physics and Astronomy, and the Department of Oncology. He is a fellow of the American Physical Society, and a fellow of the American Association for the Advancement of Science. His research focus is on tissue engineering and specifically in vitro microvessel and capillary network models of the tumor microenvironment and the blood-brain barrier.

Ilyas Singec, M.D., Ph.D.

Dr. Ilyas Singeç joined NCATS in 2015 as the director of Stem Cell Translation Laboratory in the Division of Pre-Clinical Innovation. Singeç translates stem cell discoveries into clinical applications, focusing on the development of new assays (tests), drugs and cell therapies.

Prior to joining NCATS, Singeç carried out postdoctoral work first at the National Institute of Neurological Disorders and Stroke and then at the Sanford Burnham Prebys Medical Discovery Institute in La Jolla, California, where he also served as staff scientist and director of cell reprogramming. Most recently, Singeç worked in the pharmaceutical and entrepreneurial industries.

Singeç earned his M.D. and Ph.D. summa cum laude in Germany at the Universities of Bonn and Freiburg, completing his residency in clinical neuropathology and neuroanatomy in Freiburg.

Margaret Sutherland, Ph.D.

Dr. Margaret Sutherland joined the NINDS in 2007 and serves as a Program Director in the Neurodegeneration Cluster at NINDS. She currently oversees research grant portfolios and programs in: i) Huntington's Disease; ii) Frontotemporal Dementia and iii) basic and clinical studies supporting the genetics, protein and mitochondrial dynamics, synuclein biology and stem cell based-research associated with Parkinson's Disease. Dr. Sutherland manages the CINAPS contract which is designed to support pre-clinical validation of therapeutic targets for Parkinson's Disease. Dr. Sutherland received her undergraduate degree in Microbiology and Immunology from the University of Western Ontario and her Ph.D. in Molecular Neuroscience from the Laboratory of Molecular Biology (LMB), Cambridge UK. She completed her postdoctoral training with Dr. Jeffrey Noebels, in the Department of Neurology, at the Baylor College of Medicine. Prior to joining the NINDS, Dr. Sutherland was a faculty member in the Center for Neuroscience Research at the Children's National Medical Center (CNMC), where she directed NIH-funded research programs on excitotoxicity mechanisms in neurodegeneration and epilepsy and served as director of the CNMC Transgenic Core facility.

Susanne Swalley, Ph.D.

Dr. Susanne Swalley is a Principal Scientist within the Mechanisms and Pathways group at Biogen. Trained as a chemist, she leads a Chemical Biology team focusing on the target deconvolution of small molecule hits emerging from phenotypic screens. Previously, she worked on biochemical and biophysical approaches to target identification as a Senior Investigator at the Novartis Institutes for Biomedical Research (NIBR), and contributed to evaluation and screening of new targets for diverse project teams at Vertex Pharmaceuticals. Susanne completed her postdoctoral training at Harvard University in the laboratories of Dr. Don Wiley and Dr. Stephen Harrison, earned her Ph.D. in chemistry from the California Institute of Technology with Dr. Peter Dervan, and holds chemistry and music degrees from Amherst College.

Katya Tsaoun, Ph.D.

Dr. Tsaoun is a scientist and entrepreneur with focus on commercialization of technological innovations in ADME and safety assessment and interest in translation of science innovations into public policy. She got her PhD in Nutritional Biochemistry at Tufts University Friedman School of Nutrition Science and Policy. Her doctoral research focused on the role of vitamin K-dependent growth factor Gas6 in the developing and aging nervous system. She completed her post-doctoral training at Harvard Medical School, where she worked on discovery of novel trafficking mechanisms of dopamine transporter and cannabinoid receptor and their roles in drug dependence. She spent most of her career developing and implementing ADME and safety assessment tools in drug discovery. In 2005 she became an entrepreneur and founded a company, Apredica, that developed, in-licensed and commercialized a number of in vitro ADME and toxicity tests, grew the company to a leader in the field and led a successful acquisition by a UK public company Cyprotex. She served on the Board of Cyprotex, managing the merged R&D team, as a CSO. Dr. Tsaoun currently serves on the scientific and advisory boards of biotech companies, charities, wellness tech companies, as well as on the review committees at the DDNS NIH study section and Alzheimer's Drug Discovery Foundation. Her current research interests are in public health, knowledge translation and implementation of evidence-based methods in healthcare, wellness/disease prevention and toxicology. Currently she is an Executive Director of Evidence-Based Toxicology Collaboration at Johns Hopkins Bloomberg School of Public Health.

John Wikswo, Ph.D.

Dr. John Wikswo is the Gordon A. Cain University Professor, the A. B. Learned Professor of Living State Physics, and Professor of Biomedical Engineering, Molecular Physiology and Biophysics, and Physics at Vanderbilt University, and the founding Director of the Vanderbilt Institute for Integrative Biosystems Research and Education (VIIBRE). Trained as a physicist, he received his B.A. degree from the University of Virginia and his PhD. from Stanford University. He has been a member of the Vanderbilt faculty since 1977. Since 2001, he has been developing microfluidics and analytical techniques for studying single cells and engineered tissue constructs. His work on

organs-on-chips focuses on the neurovascular unit, cardiac tissue, multi-well microformulators, and automated devices for perfusion, control, interrogation, and interconnection of organ chips.